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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/552,038

11/18/2005

Robert A. Wiercinski

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09/29/2008

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EXAMINER

LOVE, TREVOR M

ART UNIT

PAPER NUMBER

1611

MAIL DATE

DELIVERY MODE

09/29/2008

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/552,038	Applicant(s) WIERCINSKI ET AL.	
	Examiner TREVOR M. LOVE	Art Unit 1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11/18/2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 15 and 87-105 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 15, 87-105 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant's amendment filed 10/03/2005 is acknowledged. Per applicant's amendment claims 15 and 87-105 are pending, claims 1-14 and 16-86 are cancelled.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 100 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 100 recites the limitation occurring "after milling and before lyophilization". There is insufficient antecedent basis for this limitation in the claim since claim 99, from which claim 100 directly depends claims that the milling is of the lyophilized collagen sponge. The milling of a **lyophilized** collagen sponge can not occur before lyophilization.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 15, 87-97, 99, 101, 102 and 105 are rejected under 35 U.S.C. 102(b) as being anticipated by Ueda et al (Journal of Controlled Release).

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Ueda discloses a dehydrothermally crosslinked collagen sponge which incorporates TGF β 1 (see pages 56 and 57, sections 2.2 and 2.3, respectively). Said sponge is made by dissolving atelocollagen in a HCl aqueous solution at a pH of 3 to give a final concentration of 1.0 % weight. The solution is whipped, and then poured into plastic molds which are either a 6 mm diameter 3 mm deep mold, or a 7.5x11 cm² and 2 mm deep mold. The molded samples are then frozen, and immediately after being frozen, are freeze-dried. After freeze-drying, Ueda discloses that the sponges are crosslinked in a vacuum (see pages 56-57, section 2.2). Furthermore, Ueda discloses that when the sponge is to be placed within an animal, it is to be sterilized with ethylene oxide gas (see page 57, section 2.4). Also, Ueda discloses that when the sponges which are for implantation in an animal are impregnated with a PBS solution that the sponge is repeatedly washed with double-distilled water (see page 57, section 2.5).

Regarding claims 87-88 and 96-97, since applicant has provided an enabling disclosure of the invention, the features disclosed would inherently exist in a composition that was prepared using applicant's components and using applicant's method. Therefore, claims 87, 88, 96, and 97 are inherently taught in Ueda since Ueda anticipates the components and the method (see *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990)).

Regarding claims 99 and 101, applicant has failed to identify the criticality of the milling and sieving steps, particularly in light of claim 15 part (b) claiming that the components are in "a shape desired for end use". It is unclear how further milling and

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sieving between steps (d) and (e), as claimed in claims 99 and 101, would materially have any affect the product as claimed in claim 15.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

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Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al (Journal of Controlled Release).

The teachings of Ueda are set forth above under the section discussing 35 U.S.C. 102(b).

Ueda fails to directly envisage that progressively higher levels of water are employed from one wash to the next.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use whatever levels of water were necessary in the repeated washings disclosed in Ueda. One would have been motivated to do so to ensure the removal of the non-reacted residual reagents left on the sponge. There would be a reasonable expectation of success since higher volumes of water would allow for more rinsing to take place, which would provide more opportunity for the non-reacted residual reagents to either dissolve off of or mechanically removed from the collagen sponge.

Claim 103 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al (Journal of Controlled Release) as applied to claim 15 above, and further in view of Silver et al (U.S. Patent number 4,925,924).

The teachings of Ueda are set forth above under the section discussing 35 U.S.C. 102(b).

Ueda fails to directly disclose that the freezing involves the use of liquid nitrogen.

Silver teaches a collagen sponge that is frozen. Silver teaches conditions to achieve said freezing involve liquid nitrogen (see column 5, lines 47-62). One would have been motivated to do so with a reasonable expectation of success since Ueda and

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Silver are both teaching collagen sponges that are freeze-dried, and Silver identifies that the use of liquid nitrogen in the freeze-drying process had been known in the art for more than a decade before the disclosure of Ueda.

Claim 104 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ueda et al (Journal of Controlled Release) as applied to claim 15 above, and further in view of Mueller et al (U.S. Patent number 5,039,414).

The teachings of Ueda are set forth above under the section discussing 35 U.S.C. 102(b).

Ueda fails to directly disclose that the collagen sponge can comprise a microorganism.

Mueller teaches a sponge manufactured from collagen that can be freeze-dried (see column 5, lines 49-55). Furthermore, Mueller teaches that the sponges can be used as a substrate for known biodegrading microorganisms to be grown (see column 5, lines 18-20).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the collagen sponge of Ueda as a substrate for the microorganisms of Mueller. One would have been motivated to add the microorganisms of Mueller to the sponge of Ueda to provide the ability for the sponge of Ueda to function as a contaminant absorber. There would be a reasonable expectation of success in the combination since Mueller teaches that the sponges can be freeze-dried collagen, and can function as a substrate for said biodegrading microorganisms (see column 5, lines 18-55).

Conclusion

No claims are allowed. All claims are rejected. No claims are objected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to TREVOR M. LOVE whose telephone number is (571)270-5259. The examiner can normally be reached on Monday-Thursday 7:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached on 571-272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

TL

/Sharmila Gollamudi Landau/
Supervisory Patent Examiner, Art Unit 1611